UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

February 21, 2007

DP BARCODE: D331418, D331604, D332049, D332051

MRID : 46896401, 46889801, 46889803, 46889804, 46910202, 47034401, 47034402, 47037301

SUBJECT: CDG Solution 3000

REG. NO. OR FILE SYMBOL: 75757-E

DOCUMENT TYPE: **Product Chemistry Review**

Manufacturing-use [ ] OR **End-use Product [X]**

INGREDIENTS (PC Codes): 020503

CAS Number: 10049-04-4

TEST LAB:

SUBMITTER: CDG Research, Inc.

GUIDELINE:

COMMODITIES:

REVIEWER: Chris Jiang **ORGANIZATION: AD**

APPROVER: Karen P. Hicks **APPROVED DATE:** 2/21/07

COMMENT:

TO: **Emily Mitchell\Wanda Henson**
PM Team 32

FROM: Chris Jiang, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

APPLICANT: CDG Research, Inc.
Action code : A54
Due out date : 3/08/07

Product Formulation

Active Ingredient(s):	**% by wt.**
Chlorine Dioxide	**0.3 %**

BACKGROUND:

The registrant has submitted a rebuttal to the previous review and data to support this end-use product for water disinfection. The package includes a label, a Confidential Statement of Formula, and studies that have been identified as MRIDs 46896401, 46889801, 46889803, 46889804, 46910202, 47034401, 47034402, and 47037301.

FINDINGS:

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated July 12, 2006 and pinpunched 2/20/07 for the basic formulation) is consistent with the label declaration. This CSF supersedes all previous CSFs for the basic formulation.

2. The descriptions of the starting materials and the manufacturing\production\formulation process are **acceptable**.

3. The discussion of the formation of impurities is **acceptable**.

4. The certified limits are **acceptable**.

5. The enforcement analytical method is **unacceptable**. The submitted method is incomplete. There is no mention of how the solutions and standards are prepared. It also does not indicate the sample size. The method lists a formula, but the numbers and variables used in the formula are not explicitly defined on a weight by weight basis. The method is inconsistently written as some numbers are written on a weight by volume basis and some numbers are written in terms of ppm. The Agency prefers percentages written on a weight by weight basis.

6. The color, physical state, and odor are **acceptable** as the product is a pale yellow transparent liquid with a sharp chlorine odor.

7. The density is **acceptable** as the density was determined to be 1.0003 g/mL at 21 °C using a procedure based on ASTM D 891, Method B.

8. The pH is **acceptable** as the pH was determined to be 3.4 at 21 °C using a procedure based on ASTM Method E70.

9. The oxidation/reduction potential is **acceptable** as the product is a slight oxidizer. When mixed with powdered iron, the solution turned slightly rust-orange. After 24 hours, the solution decolorized and a rust-colored solid formed. No signs of reaction were observed when the product was mixed with water, potassium permanganate, or monoammonium phosphate.

10. The flammability is **acceptable** as it is inapplicable to the product.

11. The explodability is **acceptable** as it is inapplicable to the product.

12. The study for storage stability is **unacceptable** as the study was not done under GLP compliance and the study did not last a year. The Agency may have data on chlorine dioxide; however, it does not have data on this specific product.

13. The viscosity is **acceptable** as it was determined to be 0.9860 cSt at 21 ^{o}C using ASTM Methods D445/D446.

14. The miscibility is **acceptable** as it is inapplicable to the product.

15. The corrosion characteristics are **unacceptable**. The self-certification states that the product is not corrosive in the supplied packaging and that the product is corrosive to some metals. However, the source referenced on the self-certification does not have any data on corrosion characteristics.

16. The dielectric breakdown voltage is **acceptable** as it is inapplicable to the product.

17. For chlorinated products, the percentage of available chlorine must appear on the label on a weight by weight basis and not by a weight by volume basis.

18. The registrant wishes to waive all the acute toxicity requirements and states that the company will take the worst-case scenario which is classification of all categories with a toxicity category of I. Therefore, the acute toxicity profile of 75757-E is:

acute oral toxicity	I	Waived
acute dermal toxicity	I	Waived
acute inhalation toxicity	I	Waived
eye irritation	I	Waived
dermal irritation	I	Waived
dermal sensitization		Sensitizer

LABELING

The signal word is **DANGER**.

POISON! and a skull and crossbones are required on the label.

The precautionary statements must read, "**DANGER-POISON: CORROSIVE.** Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Do not vapor or spray mist. Wear coveralls worn over long-sleeved shirt and long pants, socks, chemical-resistant footwear, chemical-resistant gloves, goggles, face shield, or shielded safety glasses, and a respirator with an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approved number prefix TC-23C), or a canister approved for

pesticides (MSHA/NIOSH approved number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or a canister with any N, R, P, or HE prefilter." Fatal if swallowed, absorbed through skin or inhaled. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the restroom. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
The first aid statements must read:

IF SWALLOWED

-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to do so by a poison control center or doctor.
-Do not give anything by mouth to an unconscious person.

IF ON SKIN

-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

IF INHALED

-Move person to fresh air.
-If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
-Call a poison control center or doctor for further treatment advice.

IF IN EYES

-Hold eye open and rinse gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

Based on the acute toxicity profile, this product meets the qualifications for a Restricted-Use Pesticide as stated in 40 CFR 152.70. Based on these categories, this product also meets the qualifications for Child-Resistant Packaging as stated in 40 CFR 157.22.

CONCLUSIONS:

1. Product Science Branch of Antimicrobials Division finds the submission for 75757-E to be unacceptable. The registrant must correct the deficiencies discussed in the findings for successful registration to proceed.